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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
10/055,001	01/25/2002	Christopher A. Hellwell	021565-108	7679

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EXAMINER
NGUYEN, QUANG

ART UNIT	PAPER NUMBER
2636	12

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Please find below and/or attached an Office communication concerning this application or proceeding.

Application No.	Applicant(s)
10/055,001	HELLIWELL ET AL.
Examiner	**Art Unit**
Quang Nguyen, Ph D	1636

Office Action Summary

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-33 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-33 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s) _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Note that the specification as filed contains two claims numbered 28. Per 35 CFR 1.126, originally filed claims 1-32 have been renumbered as claims 1-33.

Accordingly, claims 1-33 are pending in the present application, and they are subjected to the following restrictions.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6, 11-12 and 20-21, drawn to an acceptor vector of the present invention having the recited components, wherein the promoter or promoter region (3) is recognized by RNA polymerases of a non-plant eukaryotic cell, and a kit comprising the same, classified in class 435, subclass 320.1.

II. Claims 1-12 and 20-21, drawn to an acceptor vector of the present invention having the recited components, wherein the promoter or promoter region (3) is a plant-expressible promoter, and a kit comprising the same, classified in class 435, subclass 320.1.

III. Claim 13, drawn to a vector comprising the sequence of SEQ ID NO:13, classified in class 435, subclass 320.1.

IV. Claim 14, drawn to a vector comprising the sequence of SEQ ID NO:23, classified in class 435, subclass 320.1.

V. Claim 15, drawn to a vector comprising the sequence of SEQ ID NO:24, classified in class 435, subclass 320.1.

VI. Claim 16, drawn to a vector comprising the sequence of SEQ ID NO:25, classified in class 435, subclass 320.1.

VII. Claim 17, drawn to a vector comprising the sequence of SEQ ID NO:26, classified in class 435, subclass 320.1.

VIII. Claims 18-19, drawn to an acceptor vector of the present invention having the recited components, wherein the promoter or promoter region (3) is recognized by a prokaryotic RNA polymerase, classified in class 435, subclass 320.1.

IX. Claims 22 and 24-27, drawn to a method for making a chimeric DNA construct capable of expressing a dsRNA in a eukaryotic cell comprising the recited steps, wherein the product DNA molecules are selected *in vitro*, classified in class 435, subclass 462.

X. Claims 22-27, drawn to a method for making a chimeric DNA construct capable of expressing a dsRNA in a eukaryotic cell comprising the recited steps, wherein the product DNA molecules are selected *in vivo*, classified in class 514, subclass 44.

XI. Claims 28 and 32, drawn to a method for preparing a eukaryotic non-human organism wherein the phenotypic expression of a target nucleic acid of interest is reduced or inhibited, and a eukaryotic non-human organism comprising a chimeric DNA construct of the present invention,

wherein said eukaryotic organism is not a plant, classified in class 800, subclasses 13, 25, for examples.

XII. Claims 28-29 and 32-33, drawn to a method for preparing a eukaryotic non-human organism wherein the phenotypic expression of a target nucleic acid of interest is reduced or inhibited, and a eukaryotic non-human organism comprising a chimeric DNA construct of the present invention, wherein said eukaryotic organism is a plant, classified in class 800, subclasses 278, 295, for examples.

XIII. Claim 30, drawn to a method for isolating a nucleic acid molecule involved in determining a particular trait in cells of a eukarytoic non-human organism, wherein said eukaryotic organism is not a plant, classified in class 800, subclass 3.

XIV. Claims 30-31, drawn to a method for isolating a nucleic acid molecule involved in determining a particular trait in cells of a eukaryotic non-human organism, wherein said eukaryotic organism is a plant, classified in class 800, subclass 278.

Claims 1-6, 11-12 and 20-21 link patentably distinct inventions of Groups I-II that lack the unity of invention. This is because the acceptor vectors in Groups I and II are distinct vectors. While the vector of Group I is recognized by RNA polymerases of a non-plant eukaryotic cell, the vector of Group II contains specifically a plant-expressible promoter. There is no substantial common core structure between a non-plant promoter and a plant-expressible promoter. As set forth in MPEP 803.02, unity of

invention exists if all species recited in a claim (1) shows a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

Additionally, should Applicants elect the invention of Group I or Group II, further group restriction is required. This is because claims 1 and 6 link patentably distinct inventions that lack the unity of invention. This is because the selectable markers genes in the group consisting of: (a) an antibiotic resistance gene, (b) a tRNA gene, (c) an auxotrophic marker, (d) a toxic gene, (e) a phenotypic marker, (f) an antisense oligonucelotide, (g) a restriction endonuclease, (h) a restriction endonuclease cleavage site, (i) an enzyme cleavage site, (j) a protein binding site, and (k) a sequence complementary PCR primer, are structurally distinct and they do not share a substantial common core structure. As set forth in MPEP 803.02, unity of invention exists if all species recited in a claim (1) shows a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

Claims 22 and 24-27 link patentably distinct inventions of Groups IX and X that lack the unity of invention. This is because the methods for making a chimeric construct capable of expressing a dsRNA in a eukaryotic cell in Groups IX and X have different method steps and therefore they require different technical considerations for achieving the desired results, specifically the product DNA molecule in Group IX is selected *in vitro*, whereas the product DNA molecule is specifically selected *in vivo*. As set forth in MPEP 803.02, unity of invention exists if all species recited in a claim (1) shows a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

Claims 28 and 32 link patentably distinct inventions of Groups XI and XII that lack the unity of invention. This is because the method of Group XI for preparing a non-plant eukaryotic non-human organism and a non-plant eukaryotic non-human organism have different method steps, starting materials and it requires different technical considerations for achieving the end-results from the method of Group XII for preparing a plant and a plant. The non-plant organisms containing a chimeric DNA construct of the present invention have distinct chemical as well as physical features from a plant containing a chimeric DNA construct of the present invention. As set forth in MPEP 803.02, unity of invention exists if all species recited in a claim (1) shows a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

Similarly, claim 30 link patentably distinct inventions of Groups XIII and XIV that lack the unity of invention. This is because the method of Group XIII for isolating a nucleic acid molecule involved in determining a particular trait in cells of non-plant eukaryotic non-human organism has different method steps, starting materials and it requires different technical considerations for achieving the end-results from the method of Group XIV for isolating a nucleic acid molecule involved in determining a particular trait in cells of a plant. As set forth in MPEP 803.02, unity of invention exists if all species recited in a claim (1) shows a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

Upon the allowance of the linking claims, the restriction requirement as to the linked invention shall be withdrawn and any claim(s) depending from or otherwise

including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims or the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-132(CCPA 1971). See also MPEP 804.01.

The inventions are distinct, each from the other because of the following reasons:

The compositions of Groups I-VIII are distinct. For example, the vector of Group I contains a promoter or promoter region (3) recognized by RNA polymerases of a non-plant eukaryotic cells, whereas the vector of Group II contains a plant-expressible promoter and the vector of Group VIII contains a promoter recognized by a prokaryotic RNA polymerases. Additionally, none of the vectors of Groups I, II and VIII comprises the sequence of SEQ ID NO:13, 23, 24,25 or 26 as the vectors of Groups III-VII, respectively. Furthermore, the vectors of Groups I-VIII are chemically and structurally distinct from the eukaryotic non-human organisms of Groups XI and XII.

The methods of Groups IX-XIV are distinct one from the others as they are drawn to methods having different starting materials, different method steps and therefore they require different technical considerations for achieving different desired end-results. It

is also noted that the methods of Groups IX-XIV can be practiced with at least one of the vectors in Groups I-VIII.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and separate search requirements particularly with regard to the literature search databases, it would be unduly burdensome for the examiner to search and/or consider the patentability of all the inventions in a single application. Therefore, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17 (h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (703) 308-8339.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, Gerald Leffers, Jr., Ph.D., may be reached at (703) 305-6232, or SPE, Irem Yucel, Ph.D., at (703) 305-1998.

Quang Nguyen, Ph.D.

PATENT EXAMINER
A.U. 1636